TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371	ATTORNEY'S DOCKET NUMBER 46483-0001-00-US 229798 [P-2942]
	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/528,496

INTERNATIONAL APPLICATION NO. PCT/US03/29653	INTERNATIONAL FILING DATE 22 September 2003	PRIORITY DATE CLAIMED 20 September 2002

TITLE OF INVENTION
Compstatin Analogs With Improved Activity

APPLICANT(S) FOR DO/EO/US
John D. Lambris

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.

2. ☑ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.

3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.

4. ☐ The US has been elected (Article 31).

5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))

    a. ☐ is attached hereto (required only if not communicated by the International Bureau).

    b. ☐ has been communicated by the International Bureau.

    c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).

6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).

    a. ☐ is attached hereto.

    b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).

7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))

    a. ☐ are attached hereto (required only if not communicated by the International Bureau).

    b. ☐ have been communicated by the International Bureau.

    c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.

    d. ☐ have not been made and will not be made.

8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☑ A preliminary amendment.

14. ☐ An Application Data Sheet under 37 CFR 1.76.

15. ☐ A substitute specification.

16. ☐ A power of attorney and/or change of address letter.

17. ☑ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.

18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).

19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**   Page 1 of 3

PTO-1390 (Rev. 09-2007)
Approved for use through 2/28/2010. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/528,496	PCT/US03/29653	46483-229798 [P-2942]

20.　　　Other items or information:

- Statement to Support Submission of Sequence Listing;
- Paper copy of amended sequence listing;
- Copy of Notification of Defective Response issued 2/26/08; and return postcard

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☐　　Basic national fee (37 CFR 1.492(a))... $310	$	
22. ☐　Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)............. $0 All other situations...$210	$	
23. ☐　　Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)................. $0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB... $410 All other situations...$510	$	
TOTAL OF 21, 22 and 23 =		

☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)).
The fee is **$260** for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
- 100 =	/50 =		x $260	$

Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		x　$ 50	$	
Independent claims	- 3 =		x　$210	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $370	$	
		TOTAL OF ABOVE CALCULATIONS =		$	

☐ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.		
SUBTOTAL =	$	

Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).　　　　　　　　　　　　　　+	$	
TOTAL NATIONAL FEE =	$	

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property　　　　　　+	$	
TOTAL FEES ENCLOSED =	$	
	Amount to be refunded:	$
	Amount to be charged	$

a. ☐ A check in the amount of $ _____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _50-0573___. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

> **ADVISORY:** If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended paying fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Janet E. Reed, Ph.D.
DRINKER BIDDLE & REATH LLP
One Logan Square, 18th and Cherry Streets
Philadelphia, PA 19103-6996

SIGNATURE

Janet E. Reed, Ph.D.
NAME

36,252
REGISTRATION NUMBER

<u>certification under 37 c.f.r. § 1.10</u>
I hereby certify that this paper, along with any documents referred to as being enclosed therewith, is being deposited with the United States Postal Service on _____ in an envelope as "Express Mail Post Office to Addressee," Mailing Label No. **EV 502960123 US** addressed to the Mail Stop PCT – Commissioner of Patents, P. O. Box 1450, Alexandria, VA 22313.

JUDITH MATTEO EDLER

UNITED STATES PATENT AND TRADEMARK OFFICE
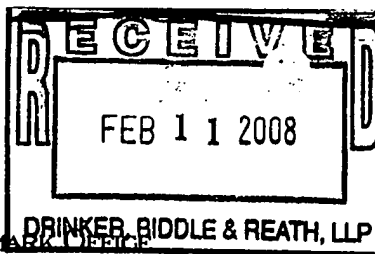
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/528,496	John D Lambris	46483-0001-00-US/P2942

23973
DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

INTERNATIONAL APPLICATION NO.	
PCT/US03/29653	
I.A. FILING DATE	PRIORITY DATE
09/22/2003	09/20/2002

CONFIRMATION NO. 4405
371 FORMALITIES LETTER

OC000000028137907

Date Mailed: 02/06/2008

NOTIFICATION OF DEFECTIVE RESPONSE

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Priority Document
- Copy of the International Application filed on 03/18/2005
- Copy of the International Search Report filed on 03/18/2005
- Biochemical Sequence Diskette filed on 02/01/2008
- Oath or Declaration filed on 12/22/2005
- Request for Immediate Examination filed on 03/18/2005
- Copy of references cited in ISR filed on 03/18/2005
- U.S. Basic National Fees filed on 03/18/2005
- Priority Documents filed on 03/18/2005
- Power of Attorney filed on 12/22/2005

Applicant's response filed 02/01/2008 is hereby acknowledged. The following requirements set forth in the NOTIFICATION of MISSING REQUIREMENTS mailed 07/05/2006 have not been completed.

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.** Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc)

page 1 of 2

sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). Refer to attachment or PAIR document dated Sequence Listing could not be accepted due to errors. See attached validation report..

Applicant is required to complete the response within a time limit of ONE MONTH from the date of this Notification or within the time remaining in the response set forth in the Notification of Missing Requirements, whichever is the longer. No extension of this time limit may be granted under 37 CFR 1.136, but the period for response set in the Notification of Missing Requirements may be extended under 37 CFR 1.136(a).

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:
- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov**

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

TRACEI A HALE

Telephone: (703) 308-9140 EXT 104

```
<400>  12

Xaa Arg Pro Pro Gly Phe Ser Ala Phe Lys Xaa Xaa
1               5               10



<210>  13
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<212>  PRT
<213>  Artificial Sequence

<220>
<223>  Synthetic Construct

<220>
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<223>  Xaa1 is Suc = succinyl

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Xaa Ala Ala Phe Xaa
1               5



<210>  14
<211>  11
<212>  PRT
<213>  Homo sapiens

<400>  14

Arg Phe Lys Phe Gln Gln Phe Phe Gly Leu Met
1               5               10



<210>  15
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<212>  PRT
<213>  Homo sapiens

<400>  15

Tyr Gly Gly Phe Met
1               5
```

****
Reviewer Comments:
<150> US 10/521,496
<151>   2005-03-18

Please change the above <150> response to US 10/528,496.

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<220>
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<223>   ACETYLATION

<220>
<221>   MOD_RES
<222>   (4)..(4)
<223>   X is 2-naphthalene

<400>   7

Ile Cys Val Xaa Gln Asp Trp Gly Ala His Arg Cys Thr
1   5   10

The above <223> response explaining Xaa at location 4 is invalid: Xaa can only represent a single amino acid, nothing else. This error also appears in Sequences 8 and 9.

```
<210>   15
<211>   13
<212>   PRT
<213>   Artificial Sequence

<220>
<223>   synthetic sequence


<220>
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<222>   (1)..(1)
<223>   X is Ile, Val, Leu, Ac-Ile, Ac-Val, Ac-Leu or a dipeptide
        comprising Gly-Ile

<220>
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<222>   (4)..(4)
<223>   X is Trp or a peptidic or non-pepdidic analog of Trp

<220>
<221>   MOD_RES
<222>   (9)..(9)
<223>   X is His, Ala, Phe or Trp

<220>°
<221>   MOD_RES
<222>   (13)..(13)
<223>   X is  L-Thr, D-Thr, Ile, Val, Gly, or a tripeptide comprising
        Thr-Ala-Asn, wherein a carboxy terminal -OH of any of the L-Thr,
        D-Thr, Ile, Val, Gly or Asn optionally is replaced by -NH2

<400>   15


Xaa Cys Val Xaa Gln Asp Trp Gly Xaa His Arg Cys Xaa
1               5                       10
```

The above explanations for Xaa at location 1 and at location 13 are

invalid: Xaa can only represent a single amino acid: it cannot
represent more than 1 amino acid.
****

Application No: 10528496   Version No: 1.0

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                    Output Set:

                Started: 2008-01-16 17:58:23.383
               Finished: 2008-01-16 17:58:26.750
                Elapsed: 0 hr(s) 0 min(s) 3 sec(s) 367 ms
         Total Warnings: 15
           Total Errors: 31
   No. of SeqIDs Defined: 15
       Actual SeqID Count: 15

Error code   Error Description

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W 213   Artificial or Unknown found in <213> in SEQ ID (2)

E 257   Invalid sequence data feature in <221> in SEQ ID (2)

W 213   Artificial or Unknown found in <213> in SEQ ID (3)

E 257   Invalid sequence data feature in <221> in SEQ ID (3)

W 213   Artificial or Unknown found in <213> in SEQ ID (4)

E 257   Invalid sequence data feature in <221> in SEQ ID (4)

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W 213   Artificial or Unknown found in <213> in SEQ ID (5)

E 257   Invalid sequence data feature in <221> in SEQ ID (5)

W 213   Artificial or Unknown found in <213> in SEQ ID (6)

E 257   Invalid sequence data feature in <221> in SEQ ID (6)

E 257   Invalid sequence data feature in <221> in SEQ ID (6)

W 213   Artificial or Unknown found in <213> in SEQ ID (7)

E 257   Invalid sequence data feature in <221> in SEQ ID (7)

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Input Set:

Output Set:

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Finished:	2008-01-16 17:58:26.750
Elapsed:	0 hr(s) 0 min(s) 3 sec(s) 367 ms
Total Warnings:	15
Total Errors:	31
No. of SeqIDs Defined:	15
Actual SeqID Count:	15

Error code		Error Description
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E	257	Invalid sequence data feature in <221> in SEQ ID (11)
E	257	Invalid sequence data feature in <221> in SEQ ID (11)

 This error has occured more than 20 times, will not be displayed

W	213	Artificial or Unknown found in <213> in SEQ ID (12)
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W	213	Artificial or Unknown found in <213> in SEQ ID (14)
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<110> Lambris, John D.

<120> Compstatin Analogs with Improved Activity

<130> 46483-0001-00-US (P2942)

<140> 10528496
<141> 2008-01-16

<150> US 10/521,496
<151> 2005-03-18

<150> PCT/US03/29653
<151> 2003-09-22

<150> US 60/412,220
<151> 2002-09-20

<160> 15

<170> PatentIn version 3.4

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<220>
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1               5                   10


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1               5                   10


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1               5                   10


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1   5   10

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1   5   10

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<220>
<223>  synthetic sequence


<220>
<221>  MOD_RES
<222>  (1)..(1)
<223>  ACETYLATION

<220>
<221>  MOD_RES
<222>  (4)..(4)
<223>  X is benzoylphenylalanine

<220>
<221>  MOD_RES
<222>  (13)..(13)
<223>  carboxylation
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<400> 13

Ile Cys Val Xaa Gln Asp Trp Gly Ala His Arg Cys Thr
1   5   10

<210> 14
<211> 16
<212> PRT
<213> Artificial sequence

<220>
<223> synthetic sequence

<220>
<221> MOD_RES
<222> (16)..(16)
<223> carboxylation

<400> 14

Gly Ile Cys Val Trp Gln Asp Trp Gly Ala His Arg Cys Thr Ala Asn
1   5   10   15

<210> 15
<211> 13
<212> PRT
<213> Artificial Sequence

<220>
<223> synthetic sequence

<220>
<221> MOD_RES
<222> (1)..(1)
<223> X is Ile, Val, Leu, Ac-Ile, Ac-Val, Ac-Leu or a dipeptide
      comprising Gly-Ile

<220>
<221> MOD_RES
<222> (4)..(4)
<223> X is Trp or a peptidic or non-pepdidic analog of Trp

<220>
<221> MOD_RES
<222> (9)..(9)
<223> X is His, Ala, Phe or Trp

<220>
<221> MOD_RES
<222> (13)..(13)
<223> X is L-Thr, D-Thr, Ile, Val, Gly, or a tripeptide comprising
      Thr-Ala-Asn, wherein a carboxy terminal -OH of any of the L-Thr,
      D-Thr, Ile, Val, Gly or Asn optionally is replaced by -NH2

<400> 15

Xaa Cys Val Xaa Gln Asp Trp Gly Xaa His Arg Cys Xaa
1   5   10